

**Appendix III.**

**Karicare First Infant Formula**

# NUTRICIA

AUSTRALIA

12<sup>th</sup> June 2001

## To whom it may concern

Nutricia Australia has marketed and sold Karicare First Infant Formula<sup>1</sup> containing LCPUFAs since 2.12.97. For the 8 months prior to this the product belonged to Douglas Pharmaceuticals. The data presented here is only relevant to the period that Nutricia has been responsible for the Karicare brand.

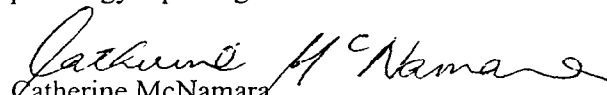
From its launch, in February 1997, the product was presented as a unit of standard infant formula with 7 capsules of tuna oil and GLA attached under the can lid. (Caregivers would add 7 drops of the oil mixture to prepared formula). From December 1998 onwards 0.2% DHA & 0.4% AA were encapsulated into the final product.

Since the end of 1997, 584,963 units<sup>2</sup> of Karicare formula containing LCPUFAs have been distributed from this facility to retail pharmacy and grocery. Each unit is reconstituted to 6.25 litres. If it assumed that the average feed is 125mls the total sales represent 3.65 million feeds.

In that time, 204 complaints have been registered with Nutricia with 24 complaints referring to an baby ill. The other complaints related to missing scoops, can not full, foreign body, poor miscibility.

In all cases, Nutricia attempts to retrieve the product from the consumer and have it tested by our manufacturer. To date the results have all meant with specifications. It is not Nutricia policy to refer infants to a medical practitioner though in some cases parents do get a medical opinion. Nutricia is unaware of the outcome of these visits.

In reference to the implication of fish oil in SIDS cases I can only refer you to the SIDS website at [www.sidsaustralia.org.au](http://www.sidsaustralia.org.au). There are comprehensive requirements for the pathology reporting on these cases.

  
Catherine McNamara  
National Marketing Manager

<sup>1</sup> As of January 2001, Karicare First Infant Formula has been trading as Karicare Gold 1. An additional LCPUFA product, Karicare Gold 2 was launched into the marketplace at the same time. The sales figures incorporate Karicare Gold 2.

<sup>2</sup> Of the 584,963 units of Karicare LCPUFA product sold by Nutricia only 16,060 were the first generation product.